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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,667	10/04/2001	Aaron J.W. Hsueh	STAN072CON	8958

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/682,667

Applicant(s)

HSUEH ET AL.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1-19 have been cancelled.

Claims 20-29 are pending.

***Claim Rejections - 35 USC § 112***

Claims 20-27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the screening for compounds that mimic Bok function. The claims, read in light of the specification are drawn to a genus of Bok polypeptides. Applicant has only discloses two full length species, human and rat, of Bok and does not teach the common structure or features of Bok proteins. Absent such disclosure, the structures of two Bok proteins are not sufficiently descriptive of a representative number of species encompassed by the genus. Therefore, the specification does not describe the claims genus in such full, clear, concise and exact terms to indicate that applicant's had possession of the genus at the time of filing of the present application.

Claims 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to "agents" that mimic Bok function, applicant has not provided sufficient written description to empower one skilled in the art to determine what types of the multitude of compounds currently known could alter Bok function. Applicant has not disclosed that there is a certain conformational structure needed by the "agent" and what types of conformations generally alter the function. If there is no special conformation, then is there a specific domain or consensus sequence? The term "agent" read on polypeptides, proteins, small and large nucleic acid sequences, small organic molecules and antibodies. This is clearly a huge genus and one would not be able to envisage the structure of 'agents' encompassed by the claims without guidance.

Therefore, the specification does not describe the claims genus in such full, clear, concise and exact terms to indicate that applicant's had possession of the genus at the time of filing of the present application.

Claims 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims and discloses the in vitro or in vivo screening for agents that mimic Bok function. The state of the art does not recognize that compounds that

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interact with Bok can alter its function. Applicant has not provided any examples in which he has successfully identified a compound that can mimic Bok function.

Applicant has not disclosed that there is a certain conformational structure needed by the "agent" and what types of conformations generally alter the function. If there is no special conformation, then is there a specific domain or consensus sequence? The term "agent" read on polypeptides, proteins, small and large nucleic acid sequences, small organic molecules and antibodies. This is clearly a huge genus and one would not be able to identify such "agents" without undue experimentation.

Even if an agent is identified in vitro, there is no evidence of record to show that the agent would reach its target in vivo. Because of pharmacokinetic factors such as the stability of the peptides in the body, half-life, absorption efficiency, binding affinity for target cells, biotransformation, and the rate of clearance from the body, there is no assurance that the agent would have the desired effect in vivo.

Thus, in view of the above, it is the Examiner's position that undue experimentation would be required by one skilled in the art to make and use the claimed invention.

### ***Conclusion***

The claims are free from the art of record because the prior art does not teach SEQ ID No. 2, 4, 6, or 8.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-

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7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh  
August 8, 2003